

Appendix G

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July 28, 1995

#MED-ESRD-95-13

TO: ALL MEDICARE DIALYSIS CENTERS

FROM: Kathie Fox, Communications Assistant
Provider Relations Department

SUBJECT: FRAUD AND ABUSE

As we have discussed in past meetings, fraud and abuse against the Medicare program is a major concern of Medicare contractors and the Health Care Financing Administration (HCFA), an agency within the Department of Health and Human Services (HHS), which is responsible for overseeing the Medicare program.

This widespread problem adversely affects everyone. In an effort to protect Medicare consumers and providers, the contractors are emphasizing the detection and prevention of fraud and abuse.

The fraud unit plays an important part in assuring the quality of the Medicare program. The unit is responsible for developing and referring fraud cases to the Office of Inspector General (OIG) when appropriate.

The OIG's Office of Investigations is responsible for the investigation of the case referred by the fraud unit. The investigation may lead to criminal convictions, civil monetary penalties or administrative sanctions.

In an effort to keep providers informed on issues of fraud and abuse, we are furnishing you a copy of the national fraud alerts. While not all of these alerts will be of concern to you as a provider, we hope keeping you abreast of all the alerts will help you protect yourselves and your patients.

If you identify potential schemes to defraud the Medicare program, please write or call the fraud unit at:

MEDICARE PROGRAM INTEGRITY CC380
BLUE CROSS AND BLUE SHIELD OF KANSAS
1133 SW TOPEKA BLVD
TOPEKA KS 66629-0001
(913) 291-7687

Additional alerts will be forwarded as they are received.

jw
KCKS
Enclosure

OIG NATIONAL FRAUD ALERTS
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Alert 1 - Seat Lift Chairs

A recent Ohio Medicare carrier audit has identified several false

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billing schemes being perpetrated by a durable medical equipment (DME) supplier. These schemes involve false billings to the Ohio carrier for repairs to seat lift chairs previously sold by the supplier.

In one scheme, the supplier billed for more repair hours than were actually used. In a second scheme, the supplier billed for repair time for beneficiaries out of state when no repairs were performed by the provider (parts were mailed to the beneficiaries who repaired the chairs themselves). Finally, the supplier billed for repairs of seat lift chairs still under warranty.

The Medicare Carrier's Manual, section 2100.4, provides that Medicare payments be made for service and maintenance of DME after the expiration of the warranty. The service and maintenance is billed under the HCFA Common Procedure Coding System (HCPCS) code E1350 with an "MS" modifier. Additionally, HCPCS provides further codes to be placed in the quantity billed field on the HCFA-1500 claim form which specifies the amount of time used to repair the DME.

Alert 2 - Upcoded Psychotherapy Sessions

A current investigation conducted by the OIG has revealed multiple fraudulent billing practices by a psychiatric group.

The investigation has revealed that psychiatrist "A" routinely billed for upcoded psychotherapy sessions. The Physician's Current Procedural Terminology (CPT) manual indicates several psychiatric therapeutic procedures should be billed based on a time frame. Code 90843 reflects individual psychotherapy by a physician for approximately 20 to 30 minutes and code 90844 reflects individual psychotherapy by a physician for approximately 45 to 50 minutes. Psychiatrist "A" routinely saw the patient for a 30-minute session, but billed for the 50-minute session.

Psychiatrist "B" had a large inpatient clientele. He routinely billed and was paid for both code 90844 and 90862 (drug management) on the same service date. The CPT manual indicates that drug management should be included under codes 90841* (for an unspecified time frame), 90843 and 90844. If drug management is billed under code 90862, along with codes 90841*, 90843, or 90844 on the same day, it is considered an overpayment.

*CPT code 90841 is a non-covered Medicare service.

Alert 3 - Van Transports

An ongoing investigation conducted by the OIG found that vans were being used to transport patients from one hospital to another, and that these trips were billed to Medicare and Medicaid programs as though an ambulance had been used for the transfer. In this case, the Indian Health Service, under a 638 tribal contract, arranged for the provision of field ambulance service and clinic transports for Native Americans on a reservation. Under the terms of the contract, ambulances were leased from the General Services Administration (GSA) to be used

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for field ambulance runs and transfers of certain patients from the hospital on the reservation to other facilities which were better equipped to handle certain emergency situations. Vans were leased from GSA to provide transportation from the reservation for referral visits to specialty clinics and facilities where patients have scheduled appointments.

In this scheme, the director of the subject ambulance service used vans for transfers that should have been made by ambulance. Then, if the patient was eligible, the Medicare and/or Medicaid programs were billed as though the transfer was made by ambulance. Claim reviewers at the State agency or the carrier were unable to discern, from the face of the claim, that a trip was not taken by an ambulance.

Alert 4 - Poly-Gel Drainage Collection System

The Office of Investigations (OI) Denver Field Office has identified an abusive situation involving the marketing of a new disposable drainage bag for incontinent patients, called the Poly-Gel Drainage Collection System (gel bag). The gel bag contains sodium polyacrylate absorbent polymer (Poly-Gel) which crystallizes upon contact with liquid, turning urine into a solid mass of gel. Since the gel bag cannot be emptied, it is designed to be discarded and replaced daily. Utilization is 30 per patient per month, as compared with standard drainage bags which are used (and allowed) at the rate of 2 to 4 per month.

There is no HCPCS code for the gel bag. Claims are currently being filed under two existing codes, A4357 and A5102. Claims billed under code A4357, the standard reusable bedside drain bag, could be considered proper but only at the rate of 2 to 4 per month. Claims billed using code A5102 are fraudulent. This code is for the large rigid or expandable drainage bottle and carries a much higher reimbursement rate. It is alleged that the gel bag marketers are representing that Medicare will reimburse 30 gel bags per month under either of the HCPCS codes. Reimbursement for 30 of the less costly A4357 would exceed normal usage by 26 bags per month. The genuine A5102 bottle is replaced once each 6 months at a cost of about \$22. Monthly Medicare reimbursement for 30 of the A5102s would be approximately \$3,960 over 6 months. Industry representatives have corroborated our information and validated our concerns about the gel bag. They confirmed that gel bag claims are being erroneously reimbursed at the rate of 30 per patient per month and, in some cases, at the higher rate. They also disputed claims that the gel bag improved patient care by reducing the incidence of infection. The gel contains the same antimicrobial agent used in common over-the-counter products such as liquid soaps, lotions, and shaving products. The gel bag's primary value is as a convenience item for the hospital or nursing home staff, since the gel bag eliminates spills. The industry sources advised that the daily bag changes actually dramatically increase the opportunity to introduce infection into the catheter.

NOTE: CPT codes indicated in OIG alerts do not imply Medicare coverage.

HCFA NATIONAL FRAUD ALERTS

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Alert 1 - Incorrect Billing for Irrigation Kits and
Other Supplies

Some Medicare parenteral/enteral nutrition (PEN) patients are reportedly receiving excessive amounts of irrigation kits, and Medicare is being billed for these kits. This situation is occurring in some instances because a supplier is billing the PEN carrier for gastrostomy irrigation supplies using "B" HCPCS codes, while Medicare is concurrently being billed, through the local carrier, for the same patient for ostomy irrigation kits under "A" HCPCS codes.

The following "A" HCPCS codes have been identified as being billed with "B" HCPCS codes for the same patient:

1. Appliances and related supplies for the management of urinary incontinence (A4310-A4359; K1032-K1036; XX004-XX005);
2. Supplies related to the management of an ostomy (A4361-A4421; A4454-A4455; A5051-A5149; K0137-K0139; XX006-XX008). The "B" codes for supplies related to the administration of enteral nutrition are B4034-B4036 and B9998.

NOTE: The DMERC regional policy indicates that ostomy supplies are covered for use on patients with an ostomy which is a surgically created opening (stoma) to divert urine, feces or ileal contents outside the body.

Alert 2 - Incontinence Care Kits

A supplier of durable medical equipment (DME) and supplies is marketing incontinence care kits to other DME companies and directly to nursing homes. The marketing plan states that nursing home patients who are covered under Medicare Part B and who have a diagnosis of urinary incontinence (ICD-9 code 788.3) qualify for the kits under a special pilot program. Reportedly, beneficiaries are frequently told to ignore the copayments if they do not have insurance.

Although there seems to be some variation in the contents of the kits, generally they include most of the following items:

ITEMS	HCPCS CODES
Latex Exam Gloves	A4927
Sterile Saline	A4214 or A4323
Syringe, 60cc, prefilled with Peri-Wash Irrigation System	A4213 or A4322
Skin Barrier: Liquid, Powder or Paste	A4363

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Disposable Wash Cloth

Diaper A4554, A4335, or 4328

Lubricant A4402

Appliance Cleaner A5131

Urinary Collection Device A4328

Polybag

The kits are being presented to nursing homes with diapers included. However, in some instances, the diapers are reportedly given free, in addition to the kits, to the nursing home in exchange for the names and health insurance claim numbers (HICN's) of beneficiaries. In either case, marketing representatives obtain beneficiary HICN's and order bulk quantities of supplies billed in the beneficiary's name. However, in no case are diapers covered under Medicare.

The marketing program states that the treatment should be 3 times per day, for each incontinent patient in the facility. (In one carrier jurisdiction, Medicare is being billed \$1,800 per month, per beneficiary.) Whether or not the patient has an in-dwelling catheter does not seem relevant; everyone apparently gets the same supplies. Clearly some of the above supplies are appropriate only if the patient has an ostomy or in-dwelling catheter.

Alert 3 - Possible Kickbacks and Inappropriate Solicitation Practices: Home Health Agencies (HHAs)

A retirement center, which provides diversified health care services, is reportedly offering discounts on rent, transportation services, meals, and other services to residents if they change to a certain HHA. The beneficiaries involved were already receiving home health services from other agencies when they were approached.

Alert 4 - Possible Overutilization and Fraudulent Billing for Event Recorders

Some physiological labs are allegedly billing Medicare for the use of event recorders for patients for whom the device was not prescribed. In some cases they are allegedly guiding the beneficiary to abuse the monitor or may be billing for more tests than were actually taken. Also, some physicians may be receiving kickbacks as a result of routinely prescribing the monitors.

Examples of problems are:

- A recorder being used to test multiple patients in the same facility with a short time period;
- Patients may be called by lab employees and told to test the monitor to ensure it is working properly and then Medicare is billed for the test; or
- Patients may be instructed by lab employees to run the

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monitor at a predetermined time, whether they are experiencing the symptom or not.

Alert 5 - Screening Mammograms Billed as Diagnostic Mammograms

Some hospitals are reportedly conducting screening mammograms but submitting claims for diagnostic mammograms. Diagnostic mammograms are reimbursed at a higher rate and can be billed at a higher frequency than screening mammograms.

A screening mammogram is allowable once every two years if the patient is over age 64. A screening mammogram is for an asymptomatic (without symptoms) patient, which includes patients with a family history of breast cancer. It does not require a physician's order. Screening mammograms should be billed under CPT code 76092 and revenue code 403. Payment is based upon a fee schedule amount. A diagnostic mammogram is allowable based upon a medical necessity with no time restrictions on the frequency,

Medicare covers diagnostic mammograms only when ordered by a physician for the treatment or diagnosis of a patient's specific illness, symptom, complaint, or injury. Diagnostic mammograms should be billed under CPT code 76091 and revenue code 401. Payment is based upon a fee schedule amount.

Alert 6 - Nebulizer Drugs

Some suppliers are reportedly diluting albuterol 0.5% (J7625) with saline to create albuterol 0.083% (J7620). They then allegedly bill Medicare for the 6 units using code J7625.

Some suppliers have been found to be submitting claims for nebulizer drugs in large quantities for individual beneficiaries. In some cases, in excess of 540 units of albuterol per month, which exceeds the needs of a typical patient, have been ordered.

These alerts are provided for education and informational purposes only. They are intended to assist interested parties in obtaining additional information concerning potential fraud and to alert affected parties to the nature of the suspected fraud. They are not intended to be used as the basis for the denial of any claims or any adverse action against any provider or supplier. Such decisions must be based on facts developed independent of these alerts. These alerts are not intended to indicate, suggest or imply that any particular individual or entity, or group of individuals or entities, are associated with the activities described.

EXCLUDED PROVIDERS

The following providers have been excluded from the Medicare program. This information was obtained from the Office of Inspector General. This listing contains only those providers who were excluded from the program beginning January 1, 1995. If you need any information regarding a provider who may have been excluded prior to 1995, you can contact our office.

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Robert Coffland, DC
315 S. State St.
Iola, KS 66749
D.O.B.: 5/5/46
Authority: Section 1892/1128(b)(14)
Period of Exclusion: Indefinite
Effective Date: 1/4/95

Kevin Marshall, D.C.
3719 W. Douglas Ave.
Wichita, KS 67213
D.O.B.: 7/12/59
Authority: Section 1892/1128(b)(14)
Period of Exclusion: Indefinite
Effective Date: 1/4/95

Michael D. Petty, D.C.
12926 Sycamore Dr
Olathe, KS 66062
D.O.B.: 8/14/61
Authority: Section 1892/1128(b)(14)
Period of Exclusion: Indefinite
Effective Date: 1/4/95

Vinod Patel, MD
P.O. Box 2402
Topeka, KS 66601
D.O.B.: 2/25/47
Authority: Section 1892/1128(b)(4)
Period of Exclusion: Indefinite
Effective Date: 4/11/95

Lori Bucholz, LPN
515 E. Koenig
Grand Island, NE 68801
D.O.B.: 5/20/60
Authority: Section 1892/1128(b)(4)
Period of Exclusion: Indefinite
Effective Date 4/11/95

Gherman Zhitlovosky, MD
1300 Mercantile Tower
Kansas City, MO 64106
D.O.B.: 10/2/42
Authority: Section 1892/1128(a)(1)
Period of Exclusion: 5 years
Effective Date: 3/16/95

Randy Wheeler, DC
144 Alexander Court
Haysville, KS 67060
D.O.B.: 6/12/57
Authority: Section 1892/1128 (b)(14)
Period of Exclusion: Indefinite
Effective Date: 3/16/95

William G. Osoba, MD
Berkley Square Bldg 13, Room 1302
550 W. Central

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Wichita, KS 67203
D.O.B.: 3/10/95
Authority: 1892/1128(b)(4)
Period of Exclusion: Indefinite
Effective Date: 5/4/95

Larry A. Buck, DC
RR2
Iola, KS 66749
D.O.B.: 4/18/61
Authority: Section 1892/1128(b)(4)
Period of Exclusion: Indefinite
Effective Date: 5/4/95

Michael S. Peterson, DC
1141 NE Vivion Rd.
Kansas City, MO 64116
D.O.B.: 12/2/61
Authority: 1892/1128(b)(14)
Period of Exclusion: Indefinite
Effective Date: 4/11/95

Molly M. O'Leary, DC
c/o 6305 Brookside Plaza
Kansas City, MO 64113
D.O.B.: 5/8/56
Authority: Section 1892/1128(b)(14)
Period of Exclusion: Indefinite
Effective Date: 6/4/95

Cheryl L. Holle, MD
509B Cedar Street
Concordia, KS 66901
D.O.B.: 11/24/55
Authority: Section 1892/1128(b)(5)
Period of Exclusion: 3 years
Effective Date: 6/1/95

Anthony M. Volk, DC
1118 Carriage Road
Papillion, NE 68046
D.O.B.: 5/27/58
Authority: Section 1892/1128(b)(14)
Period of Exclusion: Indefinite
Effective Date: 6/1/95

Douglas J. Bottorff, DC
2615 Martha Truman Road
Kansas City, MO 64137
D.O.B.: 2/19/52
Authority: Section 1892/1128(b)(14)
Period of Exclusion: Indefinite
Effective Date: 6/4/95

Vance Geick, Nurse/Nurse's Aide
2730 S. 17th Street
Lincoln, NE 68502
D.O.B.: 2/4/58
Authority: Section 1892/1128(b)(14)
Period of Exclusion: Indefinite

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Effective Date: 5/4/95

REINSTATED PROVIDERS

The following providers have been reinstated in the Medicare program. This information was obtained from the Office of Inspector General. Again, this list contains only those providers reinstated in 1995.

Willie S. Cortez, MD
547 E. Elm
Lebanon, MO 65536
Reinstatement Date: 1/19/95

Andover Drug/Linus Weimer
5217 SW Meadowlark Rd.
Andover, KS 67002
Reinstatement Date: 2/13/95

Julia Weiland-Schinstock, DC
760 W. 3rd St
Hoisington, KS 67544
Reinstatement Date: 2/8/95

Appendix H

Region B DMERC Supplier Manual



Revision No. 21

March 2000

This packet contains the Region B DMERC Supplier Manual Revision No. 21

1. Study the changes, additions, or deletions on the updated pages that follow. Remove the indicated pages and insert the replacement pages. Suppliers should retain removed pages for information on codes, policies and instructions in effect prior to the effective date of the revisions. A summary of the pages to be replaced is found on the next page.

Note: These pages are updates to only some of the pages in the Supplier Manual.

DO NOT REMOVE ANY PAGES EXCEPT AS NOTED ON THE INSTRUCTION PAGE.

2. All replacement pages are indicated at the bottom of each page:
"Rev. 21 - March 2000." Look for this date to confirm you are replacing the revised pages with the correct replacement page.
3. Shaded text or codes indicate where a change has been made on the page. Entire chapters which have been added or updated will be noted on the instruction page.

The *Region B DMERC Supplier Manual* is designed to assist suppliers in the transmission of claims for durable medical equipment, prosthetics, orthotics and supplies. AdminaStar Federal will continue to advise suppliers and physicians filing DMEPOS claims in Region B of procedural changes implemented by the Health Care Financing Administration (HCFA) including: general Medicare information, claims processing issues and updates in DMERC medical policy. In addition to this update, be sure to read your *Region B DMERC Supplier Bulletin* for more information on changes of policy and claims submission.

If you have any questions, please contact Region B Provider Assistance at: (317) 577-5722, 9a.m. – 3p.m., for all Region B DMERC states.

CODING GUIDELINES:

The billing unit for most inhalation drugs is per milligram (mg.) of the drug dispensed. The billing unit of J7631, J7668, and J7669 is per 10 milligrams (10 mg.) of the drug dispensed. The billing unit of J7608 is per gram (gm.) of the drug dispensed. The billing unit of J2545 and J7682 is per 300 milligrams (300 mg.) of the drug dispensed.

When inhalation drugs are dispensed as a single drug formulation, the coding of a unit dose form or a concentrated form (see Definitions section) is determined by the formulation of the drug as it is dispensed to the patient. If a pharmacist takes a concentrated form of a single inhalation drug (e.g., 0.5% albuterol) and dilutes it to a ready-to-use concentration (e.g., 0.083% albuterol) which is then dispensed to the patient in single-dose bottles/ vials/ ampules, the inhalation solution is billed as the unit dose form, not the concentrated form.

When there is a single drug in a unit dose container, the KO modifier is added to the unit dose form code. When two or more drugs are combined by a pharmacist and dispensed to the patient in the same unit dose container, all of the drugs are billed using the unit dose form code. However, the KP modifier is added to only one of the unit dose form codes and the KQ modifier is added to the other unit dose code(s). When two or more drugs are combined, the use of the KP and KQ modifiers should result in a combination that yields the lower cost to the beneficiary.

Whenever a unit dose form code is billed, it must have either a KO, KP, or KQ modifier. If a unit dose code does not have one of these modifiers, it will be denied as an invalid code. The KO, KP, and KQ modifiers are not used with the concentrated form codes.

The concentration of the drug in the dispensed solution can be converted to mg. or gm. as follows: A solution with a labeled concentration of 1% has ten (10) mg. of drug in each milliliter (ml.) of solution. Therefore, a 0.083% albuterol solution has 0.83 mg. of albuterol in each ml. of solution. Since albuterol 0.083% solution typically comes in a 3 ml. vial/ ampule, each vial/ ampule contains 2.5 mg. of albuterol ($3 \times .83 = 2.5$). If a pharmacist provides 120 ampules of 0.083% albuterol solution each containing 3 ml., the billed units of service would be 300 (2.5×120) units (1 unit = 1 mg.) of code J7619KO. One unit of E0590 would be billed, which would represent the dispensing fee for the albuterol for the entire month.

When billing unit dose solutions which combine two or more drugs in a single container, each drug must be listed on a separate claim line. For example, if a pharmacist provides 120 ampules of a solution containing a combination of 2.5 mg. of albuterol and 20 mg. of cromolyn in each 3 ml. ampule, the pharmacist would bill J7619KQ 300 units for the albuterol ($2.5 \text{ mg} \times 120 \text{ doses} = 300$) (1 unit = 1 mg.) and J7631KP (unit dose cromolyn) 240 units ($20 \text{ mg/amp} \times 10 \text{ mg./unit} \times 120 = 240$) (1 unit = 10 mg.) for the cromolyn. One unit of E0590 would be billed which represents the dispensing fee for the combined solution for the entire month. There should be no separate billing for saline diluent.

Pharmacists should note that the correct concentration figure must be used to determine the number of mg. of drug dispensed. For example, if a pharmacist takes 0.5 ml. of a concentrated 0.5% albuterol solution and dilutes it with 2.5 ml. of saline to give a 3 ml. unit dose solution

which is dispensed to the patient, each vial contains 2.5 mg. of albuterol (0.5 ml. x 5.0 mg/ml = 2.5 mg.), not 15 mg. (3 x 5.0).

When a drug is provided in a concentration which is dilute enough that it may be administered to a patient without adding any separate diluent in a multidose container, use code J7699.

Code J7699 is also used for an inhalation drug administered by a nebulizer which does not have a valid specific J or K code. If two or more drugs are combined in the same unit dose container, bill specific J or K codes when possible and J7699 only for individual drugs which do not have a specific J or K code. Claims for drugs that are incorrectly coded J7699 instead of the appropriate specific J or K codes will be denied for invalid coding.

Code E0585 is used when a heavy duty aerosol compressor (E0565), durable bottle type large volume nebulizer (A7017), and immersion heater (E1372) are provided at the same time. If all three items are not provided initially, the separate codes for the components would be used for billing. Code A7017 is billed for a durable, bottle type nebulizer when it is used with a K0269 compressor or a separately billed E0565 compressor. Code A7017 would not be separately billed when an E0585 system was also being billed. Code E0580 (Nebulizer, durable, glass or autoclavable plastic, bottle type, for use with regulator or flow meter) describes the same piece of equipment as A7017, but should only be billed when this type of nebulizer is used with a beneficiary-owned oxygen system.

Code E1375 (Nebulizer, portable with small compressor, with limited flow) is not valid for claim submission to the DMERC. Use code E0570 or K0501 instead.

Code A4323 (Sterile saline irrigation solution, 1000 ml) is not valid for saline solutions used with nebulizers.

DOCUMENTATION:

An order for all equipment, accessories, drugs, and other supplies related to nebulizer therapy must be signed and dated by the ordering physician and kept on file by the supplier. The order for any drug must clearly specify the type of solution to be dispensed to the patient and the administration instructions for that solution. The type of solution is described by a combination of (a) the name of the drug and the concentration of the drug in the dispensed solution and the volume of solution in each container, or (b) the name of the drug and the number of milligrams/grams of drug in the dispensed solution and the volume of solution in that container. Examples of (a) would be: albuterol 0.083% 3 ml; or albuterol 0.5% 20 ml; or cromolyn 20 mg/2 ml. Examples of (b) would be: albuterol 1.25 mg. in 3 ml. saline; or albuterol 2.5 mg. and cromolyn 20 mg. in 3 ml. saline. Administration instructions must specify the amount of solution and frequency of use. Examples would be: 3 ml. qid and prn - max 6 doses / 24 hr.; or one ampule q 4 hr prn; or 0.5 ml. diluted with saline to 3.0 ml. tid and prn. A new order is required if there is a change in the type of solution dispensed or the administration instructions. For all inhalation drugs, a new order is required at least every 12 months even if the prescription has not changed.

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A narrative diagnosis and/or an ICD-9 diagnosis code describing the condition must be present on each order. An ICD-9 code describing the condition which necessitates nebulizer therapy must be included on each claim for equipment, accessories, and/or drugs.

The patient's medical record must contain information which supports the medical necessity for all equipment, accessories, drugs, and other supplies that are ordered. Except for the situations described below, this information does not have to be submitted with the claim but should be available to the DMERC on request.

Claims for K0501 must be accompanied by documentation of the need for the battery feature.

Claims to the DMERC for E0575 which were approved by a local carrier prior to transition to the DMERC must be submitted hardcopy, with a copy of the documentation demonstrating previous payment for the equipment by the local carrier.

When billing for quantities of nebulized inhalation drugs or nebulizer accessories and supplies greater than those described in the policy as the usual maximum amounts, each claim must be accompanied by a copy of the prescription(s) and physician narrative documentation supporting the medical necessity for the higher utilization.

If more than one beta-adrenergic or more than one anticholinergic inhalation drug is billed during the same month, each claim must be accompanied by a copy of the prescription(s) and physician narrative documentation supporting the medical necessity of concurrent use.

When code E1399 is billed for miscellaneous equipment or accessories, the claim must be accompanied by a clear description of the item including the manufacturer, the model name/number if applicable, and the medical necessity of the item for that patient. When code J7699 is billed for miscellaneous inhalation drugs, the claim must be accompanied by the detailed order information described above, a clear statement of the number of ampules/bottles of solution dispensed, and documentation of the medical necessity of the drug for that patient.

In all of the situations listed above, the documentation should be attached to each hard copy claim (as when physician narrative documentation is required) or entered in the HA0 record of each electronic claim.

Refer to the Supplier Manual for more information on orders, medical records, and supplier documentation.

EFFECTIVE DATE:

Claims with dates of service on or after January 1, 2000.

This is a revision of a previously published policy.

Appendix I

Local Medical Review Policies (LMRPs)**14.28 Nebulizers****HCPCS Codes**

The appearance of a code in this section does not necessarily indicate coverage.

Equipment

- E0565 Compressor, air power source, for equipment which is not self-contained or cylinder driven
- E0570 Nebulizer with compressor
- E0571 Aerosol compressor, battery powered, for use with small volume nebulizer
- E0572 Aerosol compressor, adjustable pressure, light duty for intermittent use
- E0574 Ultrasonic generator with small volume ultrasonic nebulizer
- E0575 Nebulizer, ultrasonic, large volume
- E0585 Nebulizer, with compressor and heater

Accessories

- A4619 Face tent
- A4621 Tracheostomy mask or collar
- A7003 Administration set, small volume nonfiltered pneumatic nebulizer, disposable
- A7004 Small volume nonfiltered pneumatic nebulizer, disposable
- A7005 Administration set, small volume nonfiltered pneumatic nebulizer, non-disposable
- A7006 Administration set, small volume filtered pneumatic nebulizer
- A7007 Large volume nebulizer, disposable, unfilled, used with aerosol compressor
- A7008 Large volume nebulizer, disposable, prefilled, used with aerosol compressor
- A7009 Reservoir bottle, non-disposable, used with large volume ultrasonic nebulizer
- A7010 Corrugated tubing, disposable, used with large volume nebulizer, 100 feet
- A7011 Corrugated tubing, non-disposable, used with large volume nebulizer, 10 feet
- A7012 Water collection device, used with large volume nebulizer
- A7013 Filter, disposable, used with aerosol compressor
- A7014 Filter, non-disposable, used with aerosol compressor or ultrasonic generator
- A7015 Aerosol mask, used with DME nebulizer
- A7016 Dome and mouthpiece, used with small volume ultrasonic nebulizer
- A7017 Nebulizer, durable, glass or autoclavable plastic, bottle type, not used with oxygen
- E0580 Nebulizer, durable, glass or autoclavable plastic, bottle type, for use with regulator or flowmeter
- E1372 Immersion external heater for nebulizer

used to dilute it will be separately reimbursed. Saline dispensed for the dilution of concentrated nebulizer drugs must be billed on the same claim as the drug(s) being diluted. If the unit dose form of the drug is dispensed, separate saline solution (J7051 or A7019) will be denied as not medically necessary. Water or saline in 1000 ml quantities (A7018 or A7020) are not appropriate for use by patients to dilute inhalation drugs and will therefore be denied as not medically necessary if used for this purpose. These codes are only medically necessary when used in a large volume nebulizer (A7017 or E0585).

Albuterol, bitolterol, epinephrine, isoetharine, isoproterenol, metaproterenol, and terbutaline are all bronchodilators with beta-adrenergic stimulatory effect. It would rarely be medically necessary for a patient to be using more than one of these at a time. The use of more than one of these drugs at the same time will be denied as not medically necessary without documentation of medical necessity.

Ipratropium bromide, atropine, and glycopyrrolate are all anticholinergics. It would rarely be medically necessary for a patient to be using any more than one of these at a time. The use of more than one of these drugs at the same time will be denied as not medically necessary without documentation of medical necessity.

Dornase alpha is covered for patients with cystic fibrosis (ICD-9 diagnosis 277.00) who have a history of 2 respiratory infections requiring parenteral antibiotics during the year prior to initiation of dornase alpha and have a forced vital capacity equal to or greater than 40% of predicted value.

Because of the difference in preparation costs, the allowance per mg. for a single drug dispensed as a unit dose formulation (e.g. J7619KO) will be higher than the allowance per mg. for the same drug dispensed in a concentrated form (e.g. J7618). However, if multiple inhalation drugs are dispensed in a single container, only one of the drugs (i.e., that drug billed with the KP modifier) will be reimbursed at the higher allowance, whereas the other drug(s) (i.e., those billed with the KQ modifier) will be reimbursed at the same allowance as the concentrate. (See Coding Guidelines section for explanation of the KO, KP, and KQ modifiers.)

A monthly dispensing fee (E0590) for each covered drug or combination of drugs used in a nebulizer will be paid in addition to payment for the drug or drugs. This dispensing fee will be based on the drug dispensed, and not on the number of unit dose vials dispensed. Also, if two or more drugs are combined in single unit dose vials only one dispensing fee will be paid per drug combination per month. The dispensing fee(s) must be billed on the same claim as the dispensed inhalation drug(s). A dispensing fee is not separately billable or payable for saline, whether used as a diluent or for humidification therapy.

Charges for the drugs, diluent, and dispensing fees may only be billed by the entity that actually dispenses the drug to the Medicare beneficiary and that entity must be permitted under all applicable federal, state, and local laws and regulations to dispense drugs. Only entities licensed in the state where they are physically located may bill the DMERC for nebulizer drugs.

Aerosol compressors and small volume ultrasonic generators will be grandfathered according to the provisions of the general DMERC Grandfathering policy, Sections A and B, if the approval did not conflict with national Medicare policy. In addition, if equipment with dates of service before the effective date of this policy was approved by the DMERC, it will also continue to be reimbursed. Appropriate accessories, supplies, and drugs will be covered if the equipment had been approved by the local carrier or the DMERC and the approval did not conflict with national policy. However, large volume ultrasonic generators (E0575) are not covered unless payment for the equipment was made by a local carrier prior to transition to the DMERC. For all items, even when coverage is grandfathered or continued, the frequency parameters listed in the policy will be applied. Also, coding for inhalation drugs and resulting reimbursement will be according to the DMERC policy.

Coding Guidelines

The billing unit for most inhalation drugs is per milligram (mg.) of the drug dispensed. The billing unit of

J7631, J7668, and J7669 is per 10 milligrams (10 mg.) of the drug dispensed. The billing unit of J7608 is per gram (gm.) of the drug dispensed. The billing unit of J2545 and J7682 is per 300 milligrams (300 mg.) of the drug dispensed.

The billing units of J7618, J7619 for the standard formulation of albuterol is 1 mg = 1 unit.
The billing unit of J7618, J7619 for levalbuterol is 1 mg = 2 units.

When inhalation drugs are dispensed as a single drug formulation, the coding of a unit dose form or a concentrated form (see Definitions section) is determined by the formulation of the drug as it is dispensed to the patient. If a pharmacist takes a concentrated form of a single inhalation drug (e.g., 0.5% albuterol) and dilutes it to a ready-to-use concentration (e.g., 0.083% albuterol) which is then dispensed to the patient in single-dose bottles/ vials/ ampules, the inhalation solution is billed as the unit dose form, not the concentrated form.

When there is a single drug in a unit dose container, the KO modifier is added to the unit dose form code. When two or more drugs are combined by a pharmacist and dispensed to the patient in the same unit dose container, all of the drugs are billed using the unit dose form code. However, the KP modifier is added to only one of the unit dose form codes and the KQ modifier is added to the other unit dose code(s). When two or more drugs are combined, the use of the KP and KQ modifiers should result in a combination that yields the lower cost to the beneficiary.

Whenever a unit dose form code is billed, it must have either a KO, KP, or KQ modifier. If a unit dose code does not have one of these modifiers, it will be denied as an invalid code. The KO, KP, and KQ modifiers are not used with the concentrated form codes.

The concentration of the drug in the dispensed solution can be converted to mg. or gm. as follows: A solution with a labeled concentration of 1% has ten (10) mg. of drug in each milliliter (ml.) of solution. Therefore, a 0.083% standard formulation albuterol solution has 0.83 mg. of standard formulation albuterol in each ml. of solution. Since albuterol 0.083% solution typically comes in a 3 ml. vial/ ampule, each vial/ ampule contains 2.5 mg. of albuterol ($3 \times .83 = 2.5$). If a pharmacist provides 120 ampules of 0.083% albuterol solution each containing 3 ml., the billed units of service would be 300 (2.5×120) units (1 unit = 1 mg.) of code J7619KO. One unit of E0590 would be billed, which would represent the dispensing fee for the albuterol for the entire month.

When billing unit dose solutions which combine two or more drugs in a single container, each drug must be listed on a separate claim line. For example, if a pharmacist provides 120 ampules of a solution containing a combination of 2.5 mg of albuterol and 20 mg. of cromolyn in each 3 ml. ampule, the pharmacist would bill J7619KQ 300 units for the albuterol ($2.5 \text{ mg} \times 120 \text{ doses} = 300$) (1 unit = 1 mg.) and J7631KP (unit dose cromolyn) 240 units ($20 \text{ mg./amp} \times 10 \text{ mg./unit} \times 120 = 240$) (1 unit = 10 mg.) for the cromolyn. One unit of E0590 would be billed which represents the dispensing fee for the combined solution for the entire month. There should be no separate billing for saline diluent.

Pharmacists should note that the correct concentration figure must be used to determine the number of mg. of drug dispensed. For example, if a pharmacist takes 0.5 ml. of a concentrated 0.5% albuterol solution and dilutes it with 2.5 ml. of saline to give a 3 ml. unit dose solution which is dispensed to the patient, each vial contains 2.5 mg. of albuterol ($0.5 \text{ ml.} \times 5.0 \text{ mg/ml} = 2.5 \text{ mg.}$), not 15 mg. (3×5.0).

When a drug is provided in a concentration which is dilute enough that it may be administered to a patient without adding any separate diluent in a multidose container, use code J7699.

Code J7699 is also used for an inhalation drug administered by a nebulizer which does not have a valid specific J or K code. If two or more drugs are combined in the same unit dose container, bill specific J or K codes when possible and J7699 only for individual drugs which do not have a specific J or K code. Claims for drugs that are incorrectly coded J7699 instead of the appropriate specific J or K codes will be denied for invalid coding.

Code E0585 is used when a heavy duty aerosol compressor (E0565), durable bottle type large volume nebulizer (A7017), and immersion heater (E1372) are provided at the same time. If all three items are not provided initially, the separate codes for the components would be used for billing. Code A7017 is billed for a durable, bottle type nebulizer when it is used with a E0572 compressor or a separately billed E0565 compressor. Code A7017 would not be separately billed when an E0585 system was also being billed. Code E0580 (Nebulizer, durable, glass or autoclavable plastic, bottle type, for use with regulator or flow meter) describes the same piece of equipment as A7017, but should only be billed when this type of nebulizer is used with a beneficiary-owned oxygen system.

Code A4323 (Sterile saline irrigation solution, 1000 ml) is not valid for saline solutions used with nebulizers.

Suppliers should contact the Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC) for guidance on the correct coding of these devices.

Documentation

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider" (42 U.S.C. § 1395l(e)). It is expected that the patient's medical records will reflect the need for the care provided. The patient's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available to the DMERC upon request.

An order for all equipment, accessories, drugs, and other supplies related to nebulizer therapy must be signed and dated by the ordering physician and kept on file by the supplier. The order for any drug must clearly specify the type of solution to be dispensed to the patient and the administration instructions for that solution. The type of solution is described by a combination of (a) the name of the drug and the concentration of the drug in the dispensed solution and the volume of solution in each container, or (b) the name of the drug and the number of milligrams/ grams of drug in the dispensed solution and the volume of solution in that container. Examples of (a) would be: albuterol 0.083% 3 ml; or albuterol 0.5% 20 ml; or cromolyn 20 mg/2 ml. Examples of (b) would be: albuterol 1.25 mg. in 3 ml. saline; or albuterol 2.5 mg. and cromolyn 20 mg. in 3 ml. saline. Administration instructions must specify the amount of solution and frequency of use. Examples would be: 3 ml. qid and prn - max 6 doses / 24 hr.; or one ampule q 4 hr prn; or 0.5 ml. diluted with saline to 3.0 ml. tid and prn. A new order is required if there is a change in the type of solution dispensed or the administration instructions. For all inhalation drugs, a new order is required at least every 12 months even if the prescription has not changed.

A narrative diagnosis and/or an ICD-9 diagnosis code describing the condition must be present on each order. An ICD-9 code describing the condition which necessitates nebulizer therapy must be included on each claim for equipment, accessories, and/or drugs.

The patient's medical record must contain information which supports the medical necessity for all equipment, accessories, drugs, and other supplies that are ordered. Except for the situations described below, this information does not have to be submitted with the claim but should be available to the DMERC on request.

Claims for E0571 must be accompanied by documentation of the need for the battery feature.

Claims to the DMERC for E0575 which were approved by a local carrier prior to transition to the DMERC must be submitted hardcopy, with a copy of the documentation demonstrating previous payment for the equipment by the local carrier.

When billing for quantities of nebulized inhalation drugs or nebulizer accessories and supplies greater than those described in the policy as the usual maximum amounts, each claim must be accompanied by